

**Amendment and Response Under 37 C.F.R. 1.116**

Applicant: John Greeven et al.

Serial No.: 09/823,188

Filed: March 29, 2001

Docket No.: 10004662-1 (H301.419.101)

Title: METHOD AND APPARATUS FOR DELIVERING AND REFILLING PHARMECEUTICALS

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**REMARKS**

The following remarks are made in response to the Final Office Action mailed September 27, 2004. Claims 1-21, 23-24, 31, and 40-49 have been cancelled without prejudice. Claims 22, 23, 30-32, 36, 48, and 53 were rejected. With this Response, claims 22, 25-30, 32-39, and 50-58 have been amended and new claims 59-65 have been added. Claims 22, 25-30, 32-39, 48-58, and 59-65 are pending in the application and are presented for consideration and allowance.

**Claim Rejections under 35 U.S.C. § 112**

In the Office Action, claims 22, 23, 30-32, 36, 48, and 53 were rejected under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In the Response filed June 21, 2004, Applicant previously addressed the limitation of “unpackaged pharmaceutical”, showing support for this term from the specification, and discussing the term in the context of Liff, to illustrate how the term “unpackaged pharmaceutical” differentiates Applicant’s claimed invention from Liff. These reasons are presented again for the convenience of the Examiner, and expanded upon to further illustrate the definiteness of this language, particularly in the context of distinguishing Liff.

The term “unpackaged pharmaceutical” is supported and defined in Applicant’s specification by the nature of the **reservoir** in Applicant’s appliance and the nature of the **pharmaceutical depletion guard**.

First, Applicant’s reservoir as described in the specification, supports the limitations directed to a reservoir configured to contain a plurality of doses of unpackaged pharmaceutical. First, Applicant’s intelligent drug appliance contains a reservoir and a gate or valve, with the gate or valve enabling dispensing of a precise amount of pharmaceutical. Reservoir 104 contains a supply of substances such as liquids, tablets, gasses for a treatment regimen. Applicant’s specification page 2, lines 15-19. The appliance tracks depletion of the pharmaceutical in reservoir 104 (see Applicant’s specification page 2, lines 29-31; page 4, lines 12-23; page 4, lines 26-32; page 5, lines 1-24) in contemplation of dispensing multiple doses over time, as part of the treatment regimen, where reservoir 104 holds doses which are dispensed directly from reservoir

**Amendment and Response Under 37 C.F.R. 1.116**

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Title: METHOD AND APPARATUS FOR DELIVERING AND REFILLING PHARMECEUTICALS

---

104 to the patient. Accordingly, Applicant's specification contains no mention of bottles or packages of pharmaceuticals as Applicant's intelligent drug dispensing appliance is directed toward direct dispensing of individual doses directly from its reservoir to the patient via a drug dispensing mechanism. The doses, such as a tablet, can be consumed by the patient without removal from a package.

Moreover, as described in Applicant's specification, this intelligent drug dispensing appliance also comprises a pharmaceutical level detector which determines the relative amount of pharmaceutical in the reservoir. Several embodiments of detecting the level are described (e.g., depth measurement, static pressure, measured weight – page 5, lines 9-24), and depend on having the pharmaceutical in a freely aggregated state, not packaged within a bottle. In addition, the reservoir can hold liquids or gasses, both of which fill up the reservoir and "flow" out of reservoir, such as via gate/valve 108. This feature of "flowing" clearly comports with unpackaged pharmaceuticals, such as tablets, liquid, gasses.

In contrast, Liff discloses packaged pharmaceuticals, such as bottles of pills. These bottles roll, tumble, or slide from cabinet 20. Bottles (i.e., packaged pharmaceuticals) are dispensed, not individual tablets (claim 22) or not an inhalation mist (claim 49 or 65) as claimed by Applicant. The bottles/packages in Liff would clearly inhibit detection of impending depletion of individual doses (tablets or liquid) of pharmaceutical from a reservoir (i.e., a reservoir in which the individual doses of the pharmaceutical are dispensed directly from the reservoir to the patient via a drug delivery mechanism) to enable an automated prescription refill into/for reservoir 104, as would be relevant for Applicant's appliance holding unpackaged pharmaceuticals. For these reasons, the prior art such as Liff provides additional context for understanding the claim term "unpackaged pharmaceutical".

Accordingly, the term "unpackaged pharmaceutical" is a claim limitation that is definite and that meaningfully distinguishes Applicant's claimed invention over the prior art. For these reasons, Applicant's respectfully request withdrawal of the Section 112 rejection from claims 22, 23, 30-32, 36, 48, and 53, and all claims depending therefrom.

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Docket No.: 10004662-1 (H301.419.101)

Title: METHOD AND APPARATUS FOR DELIVERING AND REFILLING PHARMECEUTICALS

---

**Claim Rejections under 35 U.S.C. § 103**

In the Office Action, claims 22-39 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Liff U.S. Patent No. 6,471,089 (herein Liff) in view of White U.S. Patent No. 6,790,198 (herein White).

Applicant's amended independent claim 22 specifies a patient's intelligent drug dispensing appliance comprising a controller, a reservoir, a drug delivery mechanism, and a data network interface. The reservoir is configured to contain a plurality of individual unit doses of an unpackaged pharmaceutical specific to an individual patient and to be dispensed over time to the individual patient, the unpackaged pharmaceutical including individual tablets to be administered to the individual patient as individual unit doses for direct use by the individual patient according to a treatment regimen. The drug delivery mechanism is, coupled to, and responsive to the controller and to the reservoir, to controllably dispense the tablets of unpackaged pharmaceutical directly from the reservoir to the individual patient in a precise amount corresponding to the individual unit doses in response to signals from the controller. The data network interface is coupled to the controller and the intelligent drug dispensing appliance is sized and shaped for placement proximate to the individual patient remote from a health care facility.

Liff is directed to an automated apparatus for dispensing bottles. The apparatus includes a cabinet housing for storing a variety of bottles of pharmaceuticals in a plurality of bins. Each bin stores a particular variety of bottles where each bottle typically contains a plurality of unit doses. See Liff at Column 2, lines 19-27. The bins are vertically-disposed columns shaped to store a plurality of bottles stacked vertically and each bottle is sealed and contains a selected number of doses. See Liff at Column 2, lines 51-54; see also Column 6, line 2 and lines 30-33; see also Column 12, lines 53-68.

First, in contrast, Applicant's claimed intelligent drug dispensing appliance has a reservoir configured to contain a plurality of individual unit doses of unpackaged pharmaceuticals (e.g., together within the reservoir). Liff fails to disclose dispensing unpackaged pharmaceutical from a reservoir, as claimed by Applicant. Instead, Liff dispenses bottles, i.e.; packaged pharmaceuticals rather than dispensing individual doses of unpackaged

**Amendment and Response Under 37 C.F.R. 1.116**

Applicant: John Greeven et al.

Serial No.: 09/823,188

Filed: March 29, 2001

Docket No.: 10004662-1 (H301.419.101)

Title: METHOD AND APPARATUS FOR DELIVERING AND REFILLING PHARMECEUTICALS

---

pharmaceuticals directly to a patient as tablets (i.e., dispensing tablets free from packaging directly from a reservoir), as claimed by Applicant.

Second, Applicant's claimed appliance specifies that the reservoir of unpackaged pharmaceutical is specific to an individual patient – not a doctor, nurse, pharmacist, clinic or hospital, and that, via a drug delivery mechanism of the appliance, it is dispensed from the reservoir directly to the patient in unpackaged form as individual tablets.

Third, Liff dispenses bottles because it is stationed in a health care facility and therefore dispenses pharmaceuticals to many different patients, not to a single patient. Accordingly, the bottles maintain separation of the different types of pharmaceuticals. Liff also uses a card reader for patients to receive a card 39 from a patient to receive their medication. See Column 6, lines 24-35. The card reader is necessary in Liff because the bottles of Liff can be dispensed to many different patients, not just one individual patient, and the card/card reader distinguishes between the different potential recipients of the bottles. Moreover, other passages in Liff further indicate that the drug dispensing cabinet in Liff is not for a single patient. See Column 6, lines 23-35 which discloses that “this embodiment is particularly useful in large institutions, such as prisons, wherein many individuals require medication on a regular basis”.

Applicant's patient's intelligent drug dispensing appliance, refers to ownership or one-to-one relationship between the appliance and a unique patient, not many patients, and that since the appliance is for a unique patient, the pharmaceutical in the reservoir need not be packaged within a bottle, nor access-triggered with a card, as in Liff's system for many patients at institutions, such as prisons. Accordingly, the limitation of the intelligent drug dispensing appliance being a patient's intelligent drug dispensing appliance invokes ownership or exclusiveness between the patient and the appliance, and consequently it is suitable for the appliance to dispense tablets, without a bottle, directly to the patient. This feature is not present in Liff, as the drug dispensing cabinet is not owned by or for exclusive use by a single patient, but used by many patients, doctors, nurses, etc, and consequently handles bottles of pills, and uses card readers to allow access to the bottles, thereby enabling differentiation between different patients, and necessarily not dispensing tablets in unbottled form directly from the cabinet.

Fourth, dispensing pharmaceuticals is not like receiving ordinary items (e.g., candy) from a common vending machine, in which any customer can legally receive the contents dispensed.

**Amendment and Response Under 37 C.F.R. 1.116**

Applicant: John Greeven et al.

Serial No.: 09/823,188

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Docket No.: 10004662-1 (H301.419.101)

Title: **METHOD AND APPARATUS FOR DELIVERING AND REFILLING PHARMACEUTICALS**

---

Pharmaceuticals require controlled dispensing to protect the patient and the public. In Applicant's claimed appliance, since it's a patient's appliance, it makes sense to direct dispense tablets directly to a patient, because the patient is the only individual receiving those tablets. In contrast, since Liff is placed in a health care facility or institution, direct dispensing of pharmaceuticals in unbottled, i.e., unpackaged form would be hazardous as any person could potentially receive the pharmaceutical and the different pharmaceuticals cannot be mixed together.

Fifth, the dispensers in Liff are not specific to a single patient, and are refilled with pharmaceuticals for many different patients.

In contrast, in Applicant's claimed patient's appliance obtains refills for a single patient only via a data network interface. The data network interface is coupled to the controller of the appliance and is configured to send, and to receive, a data message regarding the pharmaceutical over a data network through the data network interface to and from, respectively, at least one of a health care service provider and a pharmaceutical supplier. The data message from the patient's intelligent drug dispensing appliance identifies the patient for whom the unpackaged pharmaceutical is required and the identity of the pharmaceutical. Accordingly, the data message sent/received to and from Applicant's claimed patient's appliance is regarding a pharmaceutical for a single individual since it's a patient's intelligent drug dispensing appliance, and not a bottle-dispensing cabinet for multiple patients as in Liff. Therefore, Liff fails to disclose the data network interface as claimed by Applicant.

White does not dispense unpackaged pharmaceuticals in tablet form, as claimed by Applicant. Instead, White deals exclusively with an intravenous medication infusion pump 10 (i.e., IV pump). Moreover, the single word "bedside" as cited in the Office Action, when taken in context with the rest of White which relates to an institutional/hospital setting, does not convert White into a system that is remote from a health care facility, as claimed by Applicant. Rather, White clearly directed to use in hospitals and clinics, for use with a hospital information management system (HIMS). See Figure 3, which broadly illustrates an environment in which "medication is ordered, prepared, and delivered to a patient in a hospital or other institutional health care facility" (Column 7, lines 63-65). Moreover, throughout White, use of the IV pump is described with nearly constant interaction of a nurse in managing IV pump in those facilities

**Amendment and Response Under 37 C.F.R. 1.116**

Applicant: John Greeven et al.

Serial No.: 09/823,188

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Docket No.: 10004662-1 (H301.419.101)

Title: METHOD AND APPARATUS FOR DELIVERING AND REFILLING PHARMACEUTICALS

---

(Figure 3, element 27 (“medications delivered to nurse”) and element 31 (“medication administered to patient”). See Figure 5 in which nurse performs numerous data functions (elements 69, 71, 75, 79) as part of infusion (element 79 - “nurse . . . begins infusion”). See also Figure 6A (elements 132, 120, 128 – identifying nurse interaction with IV pump) and Figure 6B (elements 148, 156, 168, 174, 142 – revealing constant interaction of nurse with IV pump system).

White also discloses that “wireless communication between the doctor’s order transmitter 83, the pharmacy transmitter 88, and the IV pump transmitter 45 or between any combination or from all the components may also facilitate medical administration to a patient in a hospital or other institution or healthcare facility.”

Accordingly, White does not address a patient’s intelligent drug dispensing appliance sized and shaped for placement adjacent a patient remote from a health care facility.

White does not cure the deficiencies of Liff regarding an unpackaged pharmaceutical since White fails to disclose dispensing unpackaged pharmaceuticals in tablet form and White does not cure the deficiencies of Liff regarding size/shape of appliance for non-health care facility placement since the IV pump in White apparently is limited to placement in a health care facility.

For these reasons, Liff and/or White, alone or in combination, fail to teach or suggest Applicant’s amended independent claim 22, and therefore claim 22 is patentable and allowable over Liff and/or White. Claims 25-30, and 59-61 are allowable as well based upon their dependency from claim 22.

Applicant’s amended independent claim 32 specifies an intelligent drug dispensing system, which comprises at least one single patient intelligent drug dispensing appliance and a pharmaceutical replenishment request data server. The at least one single patient intelligent drug dispensing appliance includes a data network interface through which pharmaceutical replenishment request signals can be received, a controller and a reservoir configured to contain a plurality of individual unit doses of unpackaged pharmaceutical to be dispensed directly to an individual patient, the unpackaged pharmaceutical including individual tablets to be administered as individual unit doses according to a treatment regimen for direct use by the patient, wherein

**Amendment and Response Under 37 C.F.R. 1.116**

Applicant: John Greeven et al.

Serial No.: 09/823,188

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Docket No.: 10004662-1 (H301.419.101)

Title: METHOD AND APPARATUS FOR DELIVERING AND REFILLING PHARMACEUTICALS

---

the at least one single patient intelligent drug dispensing appliance is sized and shaped for placement proximate to the patient at a non-health care facility. The pharmaceutical replenishment request data server is in communication with the data network interface to send medication replenishment request signals to the at least one single patient intelligent drug dispensing appliance.

For substantially the same reasons as presented for patentability of claim 22, Liff and/or White fail to disclose Applicant's amended independent claim 32. In addition, Liff fails to disclose a pharmaceutical replenishment request data server that is operatively coupled to a data network and configured to receive pharmaceutical replenishment request messages from single patient drug dispensing appliances for causing replenishment of pharmaceuticals to single patient intelligent drug dispensing appliance, as claimed by Applicant in claim 32. Rather, as previously described, Liff is directed to dispensing cabinets for many patients in institutional settings.

For these reasons, Liff and/or White, alone or in combination, fail to teach or suggest Applicant's amended independent claim 32, and therefore claim 32 is patentable and allowable over Liff and/or White. Claims 33-35 and 57 are allowable as well based upon their dependency from claim 32.

Applicant's amended independent claim 36 specifies an intelligent drug dispensing system providing automatic replenishment of pharmaceuticals. The system comprises a pharmaceutical replenishment request data server operatively coupled to a data network and configured to receive pharmaceutical replenishment request messages from at least one single patient intelligent drug dispensing appliance via the data network, and to cause replenishment of pharmaceuticals to the at least one single patient intelligent drug dispensing appliance. The pharmaceutical replenishment request message is configured to replenish an unpackaged pharmaceutical in the at least one single patient intelligent drug dispensing appliance, the appliance apparatus including a controller and a reservoir configured to hold a plurality of individual doses of the unpackaged pharmaceutical and configured to dispense the doses over time from the reservoir directly to an individual patient in a plurality of discrete individual unit doses according to a treatment regimen for direct use by the patient, wherein the at least one

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Applicant: John Greeven et al.

Serial No.: 09/823,188

Filed: March 29, 2001

Docket No.: 10004662-1 (H301.419.101)

Title: METHOD AND APPARATUS FOR DELIVERING AND REFILLING PHARMACEUTICALS

---

single patient intelligent drug dispensing apparatus is sized and shaped for placement proximate to the patient at a non-health care facility.

For substantially the same reasons as presented for patentability of claim 22 and 32, Liff and/or White fail to disclose Applicant's amended independent claim 36. In addition, Liff fails to disclose a pharmaceutical replenishment request data server that is operatively coupled to a data network and configured to receive pharmaceutical replenishment request messages from single patient drug dispensing appliances for causing replenishment of pharmaceuticals to single patient intelligent drug dispensing appliance, as claimed by Applicant in claim 36. Rather, as previously described, Liff is directed to dispensing cabinets for many patients in institutional settings.

For these reasons, Liff and/or White, alone or in combination, fail to teach or suggest Applicant's amended independent claim 36, and therefore claim 36 is patentable and allowable over Liff and/or White. Claims 37-39 are allowable as well based upon their dependency from claim 36.

In the Office Action, claims 53 and 56 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Shusterman U.S. Patent No. 6,471,087 (herein Shusterman) in view of White.

Applicant's amended independent claim 53 specifies a patients' intelligent drug dispensing appliance comprising a controller, a reservoir, a drug delivery mechanism, a data network interface, and a pharmaceutical depletion guard. The reservoir is configured to contain a supply of unpackaged pharmaceutical specific to the individual patient to be dispensed over time, the supply including a grouped plurality of individual unit doses of tablets. The drug dispensing mechanism is coupled to, and responsive to, the controller and to the reservoir to dispense the tablets of unpackaged pharmaceutical directly to the individual patient from the reservoir in a precise amount of the individual unit doses in response to signals from the controller. The data network interface coupled to the controller. The pharmaceutical depletion guard includes a pharmaceutical level detector coupled to the controller and the data network interface, the data network interface is capable of sending a message to at least one of a health care provider and pharmaceutical supplier, the data message from the data network interface including a value of a measured amount of the tablets of unpackaged pharmaceutical in the

**Amendment and Response Under 37 C.F.R. 1.116**

Applicant: John Greeven et al.

Serial No.: 09/823,188

Filed: March 29, 2001

Docket No.: 10004662-1 (H301.419.101)

Title: **METHOD AND APPARATUS FOR DELIVERING AND REFILLING PHARMACEUTICALS**

---

reservoir. The intelligent drug dispensing appliance is sized and shaped for placement proximate to the individual patient remote from a health care facility.

Shusterman fails to disclose Applicant's independent claim 53 of an intelligent drug dispensing appliance that includes a reservoir that is configured to contain a supply of unpackaged pharmaceutical to be dispensed over time to the individual patient, the supply including a grouped plurality of individual unit doses (i.e., individual unit doses grouped together within the reservoir). Instead, Shusterman discloses a compartmentalized carousel in which individual unit doses are separated from each other into different compartments and are not grouped together within a reservoir, as claimed by Applicant.

In addition, Shusterman fails to disclose Applicant's claimed intelligent drug dispensing appliance including a pharmaceutical depletion guard including a pharmaceutical level detector coupled to the controller and the data network interface, wherein the data network interface is capable of sending a message to at least one of a health care provider and pharmaceutical supplier, the data message from the data network interface including a value of a measured amount of unpackaged pharmaceutical in the reservoir.

For substantially the same reasons as previously described for patentability of claim 22, White does not address delivery of a pharmaceutical in tablet form, and does not disclose appliance remote from a health care facility. For those reasons, White does not address a direct-to-patient drug dispensing appliance sized and shaped for placement adjacent a patient remote from a health care facility, such as hospital or clinic.

White does not cure the deficiencies of Shusterman regarding grouped unpackaged pharmaceuticals in tablet form. White also does not suggest modifying its system, dealing exclusively with IV pumps, to handle tablet form medications, and Shusterman does not suggest modifying its system to handle/administer IV fluid infusion, which is taught in White.

For these reasons, Schusterman and/or White fail to teach or suggest Applicant's claim 53, and therefore claim 53 is patentable and allowable over Shusterman and White. Claims 54-56, 58, and 62-64 are allowable based on their dependency from claim 53.

**Amendment and Response Under 37 C.F.R. 1.116**

Applicant: John Greeven et al.

Serial No.: 09/823,188

Filed: March 29, 2001

Docket No.: 10004662-1 (H301.419.101)

Title: METHOD AND APPARATUS FOR DELIVERING AND REFILLING PHARMACEUTICALS

---

In the Office Action, claim 49 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Liff in view of White and further in view of Monkhouse et al. U.S. Patent No. 6,514,518 (herein Monkhouse).

Claim 49 has been canceled and rewritten into independent form as new independent claim 65 with additional limitations. Applicant's independent claim 65 specifies an intelligent direct-to-patient drug dispensing appliance. The appliance comprises a controller, a reservoir, a drug delivery mechanism, and a data network interface. The reservoir is configured to contain a plurality of individual unit doses of an unpackaged pharmaceutical specific to an individual patient and to be dispensed over time to the individual patient, the unpackaged liquid pharmaceutical to be administered to the individual patient as individual unit doses for direct use by the individual patient according to a treatment regimen. The drug delivery mechanism is coupled to, and responsive to, the controller and to the reservoir, to controllably dispense the unpackaged liquid pharmaceutical directly from the reservoir, via an ink-jet print mechanism, as a mist for inhalation to the individual patient in a precise amount corresponding to the individual unit doses in response to signals from the controller. The data network interface is coupled to the controller. The intelligent drug dispensing appliance is sized and shaped, single patient use remote from a health care facility.

First, for the substantially the same reasons presented for the patentability of Applicant's amended independent claim 22, Liff and/or White fail to teach or suggest Applicant's new independent claim 65. Moreover, both Liff and White fail to disclose an ink-jet print mechanism as a drug dispensing mechanism. Monkhouse fails to disclose dispensing an unpackaged pharmaceutical directly to the individual patient from a reservoir as a mist, as claimed by Applicant, with or without an ink-jet mechanism.

Moreover, Monkhouse is limited to using an ink-jet head to build a solid dosage form, such as an implant. Even if this form is a "standard format", which Applicant does not admit, it does not equate with "dispensing a mist for inhalation" as claimed by Applicant. Applicant has not claimed dispensing drugs generally in a standard format, but claimed dispensing a pharmaceutical directly to a patient as a mist for inhalation.

In particular, in Monkhouse the inkjet mechanism is used only for building the implant, not for dispensing directly to a patient. Accordingly, only after being built via three-dimensional

**Amendment and Response Under 37 C.F.R. 1.116**

Applicant: John Greeven et al.

Serial No.: 09/823,188

Filed: March 29, 2001

Docket No.: 10004662-1 (H301.419.101)

Title: **METHOD AND APPARATUS FOR DELIVERING AND REFILLING PHARMECEUTICALS**

---

printing (3DP), the dosage form is then dispensed to the patient, such as by implanting the solid dosage form into the patient. See Monkhouse Column 2, lines 10-24; Column 3, lines 7-8, lines 41-45. Accordingly, the ink-jet head in Monkhouse is not associated with directly dispensing a liquid pharmaceutical as a mist for inhalation by a patient – its only associated with building a solid pharmaceutical for later insertion into a patient as an implant. See Monkhouse at Column 4, lines 44-48 (e.g., “printhead 22 deposits fluid 24 onto the powder layer .... And the process is repeated until the dosage forms are completed”).

Applicant does not claim an implant-making appliance. Monkhouse does not disclose a direct-to-patient drug dispenser. Fluid 24 in Monkhouse is not inhaled by the patient, nor is the implant ingested by the patient. A patient does not directly receive the pharmaceutical in Monkhouse from 3DP printing, only after printing and implantation under the skin.

Moreover, there is no suggestion in either Liff or Monkhouse to modify the system of Liff or to modify the system of Monkhouse, much less combine Liff and Monkhouse to achieve Applicant’s claimed system. Monkhouse and Liff are not analogous devices/systems, as one deals with dispensing bottles at an institution and the other deals with manufacturing implants. Likewise, there is no suggestion in either White or Monkhouse to modify the system of White or to modify the system of Monkhouse, much less combine White and Monkhouse to achieve Applicant’s claimed appliance. Monkhouse and White are not analogous devices/systems, as one deals with pumping IV fluids from a pump at a health care facility and the other deals with manufacturing implants.

For these reasons, Liff, White, and Monkhouse, alone or in combination, fail to teach or suggest Applicant’s independent claim 65, and therefore claim 65 is patentable, and allowable over Liff, White, and Monkhouse. Claims 50-52 and 65 are believed to be allowable based on their dependency from independent claim 65.

In the Office Action, claim 52 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Liff in view of White and further in view of O’Brien U.S. Patent No. 5,963,136 (herein in O’Brien).

Claim 52 is believed to be patentable over Liff, White and O’Brien based upon its dependency from patentably distinct claim 65, and intervening claims 50-51.

**Amendment and Response Under 37 C.F.R. 1.116**

Applicant: John Greeven et al.

Serial No.: 09/823,188

Filed: March 29, 2001

Docket No.: 10004662-1 (H301.419.101)

Title: METHOD AND APPARATUS FOR DELIVERING AND REFILLING PHARMACEUTICALS

---

**New Claims**

Applicant's presents new claims 59-61, which depend on claim 22, and new claims 62-64, which depend on claim 53. Applicant also presents new claims 65-66. Favorable consideration of these claims is respectfully requested.

**CONCLUSION**

In view of the above, Applicant respectfully submits that pending claims 22, 25-30, 32-39, 50-58, and 59-66 are in form for allowance and are not taught or suggested by the cited references. Therefore, reconsideration and withdrawal of the rejections and allowance of claims 22, 25-30, 32-39, 50-58, and 59-66 is respectfully requested.



**Amendment and Response Under 37 C.F.R. 1.116**

Applicant: John Greeven et al.

Serial No.: 09/823,188

Filed: March 29, 2001

Docket No.: 10004662-1 (H301.419.101)

Title: METHOD AND APPARATUS FOR DELIVERING AND REFILLING PHARMECEUTICALS

No fees are required under 37 C.F.R. 1.16(b)(c). However, if such fees are required, the Patent Office is hereby authorized to charge Deposit Account No. 50-0471.

The Examiner is invited to contact the Applicant's representative at the below-listed telephone numbers to facilitate prosecution of this application.

Respectfully submitted,

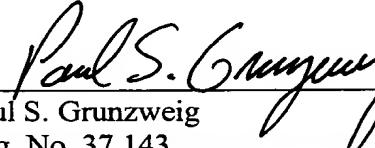
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**CERTIFICATE UNDER 37 C.F.R. 1.8:** The undersigned hereby certifies that this paper or papers, as described herein, are being deposited in the United States Postal Service, as first class mail, in an envelope address to: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 16th day of November, 2004.

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